1	PHARMAC	Y BENEFIT MANAGER A	MENDMENTS
2		2019 GENERAL SESSION	
3		STATE OF UTAH	
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5		Senate Sponsor: Evan J. Vick	cers
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18			
19	LONG TITLE		
20	General Description:		
21	This bill amends and cr	eates requirements for pharmacy be	enefit managers.
22	Highlighted Provisions:		
23	This bill:		
24	creates a pharmacy	benefit manager license;	
25	requires a person w	ho acts as a pharmacy benefit mana	ger in the state to be licensed
26	by the Insurance Department; and		
27	 creates certain opera 	ating and reporting requirements for	r pharmacy benefit managers.

Money Appropriated in this Bill:

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9	None
0	Other Special Clauses:
1	This bill provides a special effective date.
2	Utah Code Sections Affected:
3	AMENDS:
4	31A-2-201.2, as last amended by Laws of Utah 2018, Chapter 319
5	ENACTS:
6	31A-46-101, Utah Code Annotated 1953
7	31A-46-102, Utah Code Annotated 1953
8	31A-46-201 , Utah Code Annotated 1953
9	31A-46-202, Utah Code Annotated 1953
0	31A-46-301, Utah Code Annotated 1953
-1	31A-46-304, Utah Code Annotated 1953
2	31A-46-401, Utah Code Annotated 1953
3	31A-46-402, Utah Code Annotated 1953
4	RENUMBERS AND AMENDS:
5	31A-46-302, (Renumbered from 58-17b-626, as enacted by Laws of Utah 2018,
6	Chapter 305)
7	31A-46-303, (Renumbered from 31A-22-640, as last amended by Laws of Utah 2015,
8	Chapter 258)
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0	Be it enacted by the Legislature of the state of Utah:
1	Section 1. Section 31A-2-201.2 is amended to read:
2	31A-2-201.2. Evaluation of health insurance market.
3	(1) Each year the commissioner shall:
4	(a) conduct an evaluation of the state's health insurance market;
5	(b) report the findings of the evaluation to the Health and Human Services Interim
6	Committee before December 1 of each year; and

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57	(c) publish the findings of the evaluation on the department website.
58	(2) The evaluation required by this section shall:
59	(a) analyze the effectiveness of the insurance regulations and statutes in promoting a
60	healthy, competitive health insurance market that meets the needs of the state, and includes an
61	analysis of:
62	(i) the availability and marketing of individual and group products;
63	(ii) rate changes;
64	(iii) coverage and demographic changes;
65	(iv) benefit trends;
66	(v) market share changes; and
67	(vi) accessibility;
68	(b) assess complaint ratios and trends within the health insurance market, which
69	assessment shall include complaint data from the Office of Consumer Health Assistance within
70	the department;
71	(c) contain recommendations for action to improve the overall effectiveness of the
72	health insurance market, administrative rules, and statutes; [and]
73	(d) include claims loss ratio data for each health insurance company doing business in
74	the state[:]; and
75	(e) include information about pharmacy benefit managers collected under Section
76	<u>31A-46-301.</u>
77	(3) When preparing the evaluation and report required by this section, the
78	commissioner may seek the input of insurers, employers, insured persons, providers, and others
79	with an interest in the health insurance market.
80	(4) The commissioner may adopt administrative rules for the purpose of collecting the
81	data required by this section, taking into account the business confidentiality of the insurers.
82	(5) Records submitted to the commissioner under this section shall be maintained by
83	the commissioner as protected records under Title 63G, Chapter 2, Government Records
84	Access and Management Act

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Section 2. Section 31A-46-101 is enacted to read:	
CHAPTER 46. PHARMACY BENEFIT MANAGER LICENS	SING ACT

85	Section 2. Section 31A-46-101 is enacted to read:
86	CHAPTER 46. PHARMACY BENEFIT MANAGER LICENSING ACT
87	Part 1. General Provisions
88	31A-46-101. Title.
89	This chapter is known as the "Pharmacy Benefit Manager Licensing Act."
90	Section 3. Section 31A-46-102 is enacted to read:
91	31A-46-102. Definitions.
92	As used in this chapter:
93	(1) "Administrative fee" means any payment, other than a rebate, that a pharmaceutical
94	manufacturer makes directly or indirectly to a pharmacy benefit manager.
95	(2) "Contracting insurer" means an insurer as defined in Section 31A-22-636 with
96	whom a pharmacy benefit manager contracts to provide a pharmacy benefit management
97	service.
98	(3) "Pharmacist" means the same as that term is defined in Section 58-17b-102.
99	(4) "Pharmacy" means the same as that term is defined in Section 58-17b-102.
100	(5) "Pharmacy benefits management service" means any of the following services
101	provided to a health benefit plan, or to a participant of a health benefit plan:
102	(a) negotiating the amount to be paid by a health benefit plan for a prescription drug; or
103	(b) administering or managing a prescription drug benefit provided by the health
104	benefit plan for the benefit of a participant of the health benefit plan, including administering
105	or managing:
106	(i) a mail service pharmacy;
107	(ii) a specialty pharmacy;
108	(iii) claims processing;
109	(iv) payment of a claim;
110	(v) retail network management;
111	(vi) clinical formulary development;

(vii) clinical formulary management services;

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113	(viii) rebate contracting;
114	(ix) rebate administration;
115	(x) a participant compliance program;
116	(xi) a therapeutic intervention program;
117	(xii) a disease management program; or
118	(xiii) a service that is similar to, or related to, a service described in Subsection (5)(a)
119	or (5)(b)(i) through (xii).
120	(6) "Pharmacy benefit manager" means a person licensed under this chapter to provide
121	a pharmacy benefits management service.
122	(7) "Pharmacy service" means a product, good, or service provided to an individual by
123	a pharmacy or pharmacist.
124	(8) (a) "Rebate" means a refund, discount, or other price concession that is paid by a
125	pharmaceutical manufacturer to a pharmacy benefit manager based on a prescription drug's
126	utilization or effectiveness.
127	(b) "Rebate" does not include an administrative fee.
128	Section 4. Section 31A-46-201 is enacted to read:
129	Part 2. Licensure
130	31A-46-201. License required.
131	(1) A person may not perform, offer to perform, or advertise any pharmacy benefits
132	management service in the state unless the person is licensed as a pharmacy benefit manager
133	under this chapter.
134	(2) A person may not utilize the services of another person as a pharmacy benefit
135	manager if the person knows or has reason to know that the other person does not have a
136	license under this chapter.
137	Section 5. Section 31A-46-202 is enacted to read:
138	31A-46-202. Application for licensure.
139	(1) To obtain or renew a license as a pharmacy benefit manager, a person shall:
140	(a) submit an application to the commissioner on forms and in a manner established by

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141	the commissioner by rule made in accordance with Title 63G, Chapter 3, Utah Administrative
142	Rulemaking Act; and
143	(b) pay a licensure fee established by the department in accordance with Section
144	<u>31A-3-103.</u>
145	(2) (a) The commissioner may require an applicant to submit information or
146	documentation regarding the management and ownership of the pharmacy benefit manager in
147	the application described in Subsection (1)(a).
148	(b) Any material change in the information submitted in an application described in
149	Subsection (1)(a) shall be reported to the department within 30 days after the day on which the
150	information changes.
151	(3) The term of a license issued under this section is one year.
152	Section 6. Section 31A-46-301 is enacted to read:
153	Part 3. Operating Requirements
154	31A-46-301. Reporting requirements.
155	(1) Before April 1 of each year, a pharmacy benefit manager operating in the state shall
156	report to the department, for the previous calendar year:
157	(a) any insurer, pharmacy, or pharmacist in the state with which the pharmacy benefit
158	manager had a contract;
159	(b) the total value, in the aggregate, of all rebates and administrative fees that are
160	attributable to enrollees of a contracting insurer; and
161	(c) the percentage of aggregate rebates that the pharmacy benefit manager retained
162	under the pharmacy benefit manager's agreement to provide pharmacy benefits management
163	services to a contracting insurer.
164	(2) Records submitted to the commissioner under Subsections (1)(b) and (c) are a
165	protected record under Title 63G, Chapter 2, Government Records Access and Management
166	Act.
167	(3) (a) The department shall publish the information provided by a pharmacy benefit
168	manager under Subsection (1)(c) in the annual report described in Section 31A-2-201.2.

169	(b) The department may not publish information submitted under Subsection (1)(b) or
170	(c) in a manner that:
171	(i) makes a specific submission from a contracting insurer or pharmacy benefit
172	manager identifiable; or
173	(ii) is likely to disclose information that is a trade secret as defined in Section 13-24-2.
174	(c) At least 30 days before the day on which the department publishes the data, the
175	department shall provide a pharmacy benefit manager that submitted data under Subsection
176	(1)(b) or (c) with:
177	(i) a general description of the data that will be published by the department;
178	(ii) an opportunity to submit to the department, within a reasonable period of time and
179	in a manner established by the department by rule made in accordance with Title 63G, Chapter
180	3, Utah Administrative Rulemaking Act:
181	(A) any correction of errors, with supporting evidence and comments; and
182	(B) information that demonstrates that the publication of the data will violate
183	Subsection (3)(b), with supporting evidence and comments.
184	Section 7. Section 31A-46-302, which is renumbered from Section 58-17b-626 is
185	renumbered and amended to read:
186	[58-17b-626]. <u>31A-46-302.</u> Direct or indirect remuneration by pharmacy
187	benefit managers Disclosure of customer costs Limit on customer payment for
188	prescription drugs.
189	(1) As used in this section:
190	(a) "Allowable claim amount" means the amount paid by an insurer under the
191	customer's health benefit plan.
192	[(a)] (b) "Cost share" means the amount paid by an insured customer under the
193	customer's health benefit plan.
194	[(b)] (c) "Direct or indirect remuneration" means any adjustment in the total
195	compensation:
196	(i) received by a pharmacy from a pharmacy [benefits manager or coordinator] benefit

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197	manager for the sale of a drug, device, or other product or service; and
198	(ii) that is determined after the sale of the product or service.
199	[(c)] (d) "Health benefit plan" means the same as that term is defined in Section
200	31A-1-301.
201	(e) "Pharmacy reimbursement" means the amount paid to a pharmacy by a pharmacy
202	benefit manager for a dispensed prescription drug.
203	[(d)] (f) "Pharmacy services administration organization" means an entity that contracts
204	with a pharmacy to assist with third-party payer interactions and administrative services related
205	to third-party payer interactions, including:
206	(i) contracting with a pharmacy [benefits manager or coordinator] benefit manager on
207	behalf of the pharmacy; and
208	(ii) managing a pharmacy's claims payments from third-party payers.
209	[(e)] (g) "Pharmacy service entity" means:
210	(i) a pharmacy services administration organization; or
211	(ii) a pharmacy [benefits manager or coordinator] benefit manager.
212	[(f)] (h) (i) "Reimbursement report" means a report on the adjustment in total
213	compensation for a claim.
214	(ii) "Reimbursement report" does not include a report on adjustments made pursuant to
215	a pharmacy audit or reprocessing.
216	[(g)] <u>(i)</u> "Sale" means a prescription drug claim covered by a health benefit plan.
217	(2) If a pharmacy service entity engages in direct or indirect remuneration with a
218	pharmacy, the pharmacy service entity shall make a reimbursement report available to the
219	pharmacy upon the pharmacy's request.
220	(3) For the reimbursement report described in Subsection (2), the pharmacy service
221	entity shall:
222	(a) include the adjusted compensation amount related to a claim and the reason for the
223	adjusted compensation; and
224	(b) provide the reimbursement report:

225	(i) in accordance with the contract between the pharmacy and the pharmacy service
226	entity;
227	(ii) in an electronic format that is easily accessible; and
228	(iii) within 120 days after the day on which the pharmacy [benefits manager or
229	coordinator] benefit manager receives a report of a sale of a product or service by the
230	pharmacy.
231	(4) A pharmacy service entity shall, upon a pharmacy's request, provide the pharmacy
232	with:
233	(a) the reasons for any adjustments contained in a reimbursement report; and
234	(b) an explanation of the reasons provided in Subsection (4)(a).
235	(5) (a) A pharmacy [benefits manager or coordinator] benefit manager may not prohibit
236	or penalize the disclosure by a pharmacist of:
237	(i) an insured customer's cost share for a covered prescription drug;
238	(ii) the availability of any therapeutically equivalent alternative medications; or
239	(iii) alternative methods of paying for the prescription medication, including paying the
240	cash price, that are less expensive than the cost share of the prescription drug.
241	(b) Penalties that are prohibited under Subsection (5)(a) include increased utilization
242	review, reduced payments, and other financial disincentives.
243	(6) A pharmacy [benefits manager or coordinator] benefit manager may not require an
244	insured customer to pay, for a covered prescription drug, more than the lesser of:
245	(a) the applicable cost share of the prescription drug being dispensed; [or]
246	(b) the applicable allowable claim amount of the prescription drug being dispensed;
247	(c) the applicable pharmacy reimbursement of the prescription drug being dispensed; or
248	[(b)] (d) the retail price of the drug without prescription drug coverage.
249	Section 8. Section 31A-46-303, which is renumbered from Section 31A-22-640 is
250	renumbered and amended to read:
251	[31A-22-640]. 31A-46-303. Insurer and pharmacy benefit management
252	services Registration Maximum allowable cost Audit restrictions.

253	(1) [For purposes of] As used in this section:
254	(a) "Maximum allowable cost" means:
255	(i) a maximum reimbursement amount for a group of pharmaceutically and
256	therapeutically equivalent drugs; or
257	(ii) any similar reimbursement amount that is used by a pharmacy benefit manager to
258	reimburse pharmacies for multiple source drugs.
259	(b) "Obsolete" means a product that may be listed in national drug pricing compendia
260	but is no longer available to be dispensed based on the expiration date of the last lot
261	manufactured.
262	(c) "Pharmacy benefit manager" means a person or entity that provides pharmacy
263	benefit management services as defined in Section 49-20-502 on behalf of an insurer as defined
264	in Subsection 31A-22-636(1).
265	(2) An insurer and an insurer's pharmacy benefit manager is subject to the pharmacy
266	audit provisions of Section 58-17b-622.
267	(3) A pharmacy benefit manager shall not use maximum allowable cost as a basis for
268	reimbursement to a pharmacy unless:
269	(a) the drug is listed as "A" or "B" rated in the most recent version of the United States
270	Food and Drug Administration's approved drug products with therapeutic equivalent
271	evaluations, also known as the "Orange Book," or has an "NR" or "NA" rating or similar rating
272	by a nationally recognized reference; and
273	(b) the drug is:
274	(i) generally available for purchase in this state from a national or regional wholesaler;
275	and
276	(ii) not obsolete.
277	(4) The maximum allowable cost may be determined using comparable and current
278	data on drug prices obtained from multiple nationally recognized, comprehensive data sources,
279	including wholesalers, drug file vendors, and pharmaceutical manufacturers for drugs that are
280	available for purchase by pharmacies in the state.

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(5) For every drug for which the pharmacy benefit manager uses maximum allowable cost to reimburse a contracted pharmacy, the pharmacy benefit manager shall: (a) include in the contract with the pharmacy information identifying the national drug pricing compendia and other data sources used to obtain the drug price data; (b) review and make necessary adjustments to the maximum allowable cost, using the most recent data sources identified in Subsection (5)(a), at least once per week; (c) provide a process for the contracted pharmacy to appeal the maximum allowable cost in accordance with Subsection (6); and (d) include in each contract with a contracted pharmacy a process to obtain an update to the pharmacy product pricing files used to reimburse the pharmacy in a format that is readily available and accessible. (6) (a) The right to appeal in Subsection (5)(c) shall be: (i) limited to 21 days following the initial claim adjudication; and (ii) investigated and resolved by the pharmacy benefit manager within 14 business days. (b) If an appeal is denied, the pharmacy benefit manager shall provide the contracted pharmacy with the reason for the denial and the identification of the national drug code of the drug that may be purchased by the pharmacy at a price at or below the price determined by the pharmacy benefit manager. (7) The contract with each pharmacy shall contain a dispute resolution mechanism in the event either party breaches the terms or conditions of the contract. [(8) (a) To conduct business in the state, a pharmacy benefit manager shall register with the Division of Corporations and Commercial Code within the Department of Commerce and annually renew the registration. To register under this section, the pharmacy benefit

- (i) the name of the pharmacy benefit manager,
- (ii) the name and contact information for the registered agent for the pharmacy benefit manager; and

manager shall submit an application which shall contain only the following information:

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309	[(iii) if applicable, the federal employer identification number for the pharmacy benefit
310	manager.]
311	[(b) The Department of Commerce may establish a fee in accordance with Title 63J,
312	Chapter 1, Budgetary Procedures Act, for the initial registration and the annual renewal of the
313	registration, which may not exceed \$100 per year.]
314	[(c) The following entities do not have to register as a pharmacy benefit manager under
315	Subsection (8)(a) when the entity is providing formulary services to its own patients,
316	employees, members, or beneficiaries:]
317	[(i) a health care facility licensed under Title 26, Chapter 21, Health Care Facility
318	Licensing and Inspection Act;]
319	[(ii) a pharmacy licensed under Title 58, Chapter 17b, Pharmacy Practice Act;]
320	[(iii) a health care professional licensed under Title 58, Occupations and Professions;]
321	[(iv) a health insurer; and]
322	[(v) a labor union.]
323	[9] (8) This section does not apply to a pharmacy benefit manager when the
324	pharmacy benefit manager is providing pharmacy benefit management services on behalf of the
325	state Medicaid program.
326	Section 9. Section 31A-46-304 is enacted to read:
327	31A-46-304. Claims practices.
328	(1) A pharmacy benefit manager shall permit a pharmacy to collect the amount of a
329	customer's cost share from any source.
330	(2) A pharmacy benefit manager may not deny or reduce a reimbursement to a
331	pharmacy or a pharmacist after the adjudication of the claim, unless:
332	(a) the pharmacy or pharmacist submitted the original claim fraudulently;
333	(b) the original reimbursement was incorrect because:
334	(i) the pharmacy or pharmacist had already been paid for the pharmacy service; or
335	(ii) an unintentional error resulted in an incorrect reimbursement; or
336	(c) the pharmacy service was not rendered by the pharmacy or pharmacist.

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337	(3) Subsection (2) does not apply if:
338	(a) an investigative audit of pharmacy records for fraud, waste, abuse, or other
339	intentional misrepresentation indicates that the pharmacy or pharmacist engaged in criminal
340	wrongdoing, fraud, or other intentional misrepresentation; or
341	(b) the reimbursement is reduced as the result of the reconciliation of a reimbursement
342	amount under a performance contract if:
343	(i) the performance contract lays out clear performance standards under which the
344	reimbursement for a specific drug may be increased or decreased; and
345	(ii) the agreement between the pharmacy benefit manager and the pharmacy or
346	pharmacist explicitly states, in a separate document that is signed by the pharmacy benefit
347	manager and the pharmacy or pharmacist, that the provisions of Subsection (2) do not apply.
348	Section 10. Section 31A-46-401 is enacted to read:
349	Part 4. Miscellaneous
350	31A-46-401. Penalties.
351	A person that violates a provision of this chapter is subject to the penalties described in
352	Section 31A-2-308.
353	Section 11. Section 31A-46-402 is enacted to read:
354	31A-46-402. Severability.
355	If any provision of this chapter or the application of any provision of this chapter is

found invalid, the remainder of this chapter shall be given effect without the invalid provision

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or application.

Section 12. Effective date.

This bill takes effect on July 1, 2019.